

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

)
) MDL NO. 1456
) Civil Action No. 01-12257-PBS
) Subcategory Case No. 03-10643-PBS
)

THIS DOCUMENT RELATES TO:

) Judge Patti B. Saris
)

The City of New York, et al.,

v.

Abbott Laboratories, et al.

**DEFENDANT BOEHRINGER INGELHEIM ROXANE, INC.'S RESPONSE
TO PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED
MATERIAL FACTS AS TO BOEHRINGER INGELHEIM ROXANE, INC.**

Pursuant to Rule 56.1 of the Local Rules of this Court, Defendant Boehringer Ingelheim Roxane, Inc. ("Roxane") hereby submits its Response to Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts as to Boehringer Ingelheim Roxane, Inc. ("Plaintiffs' Roxane-Specific Statement"). Roxane's Specific Responses correspond to the numbered paragraphs set forth in Plaintiffs' Roxane-Specific Statement and identify those issues which are undisputed as well as those issues for which there is a genuine dispute as to one or more material facts.¹

Roxane also refers the Court to Defendants' Response to Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts Applicable to All Defendants, filed June 15, 2009 [Docket No. 6117].

On the basis of these facts, and the facts set forth in Defendants' summary judgment papers,

¹ Roxane does not respond herein to the headings in Plaintiffs' Roxane-Specific Statement. To the extent these headings purport to state or characterize facts, such facts or characterizations are not properly supported with citations to the record, as is required by Local Rule 56.1. To the extent a response is required, Roxane disputes any facts or characterizations contained in these headings.

Plaintiffs' Motion for Partial Summary Judgment should be denied and summary judgment should be entered in Defendants' favor on all claims that New York Medicaid paid or should have paid on the basis of FUL.

INTRODUCTION

Plaintiffs' Roxane-Specific Statement should be rejected for its failure to comply with Local Rule 56.1. The Rule requires Plaintiffs to include "a concise statement of the *material facts of record* as to which the moving party contends there is *no genuine issue to be tried*, with page references to affidavits, depositions and other documentation." Local Rule 56.1 (emphasis added). Many of the assertions in Plaintiffs' Roxane-Specific Statement lack citations to factual support in the record. Even where Plaintiffs provide citations to factual support in the record, the cited material rarely supports the "fact" for which it is cited. Often, the record shows exactly the opposite of what Plaintiffs claim. Plaintiffs' Roxane-Specific Statement also offers "facts" that are plainly not material to Plaintiffs' partial summary judgment motion on issues related to the Federal Upper Limit ("FUL"). Finally, many of the purported "facts" are argumentative and conclusory assertions. Because of Plaintiffs' failure to comply with Local Rule 56.1, their Roxane-Specific Statement should be rejected, and their motion for partial summary judgment should be denied. *See, e.g., Dale v. H.B. Smith Co., Inc.*, 910 F. Supp. 14, 20 (D. Mass. 1995) (denying summary judgment motion when party made 56.1 statements that were argumentative, conclusory, and unsupported by record evidence).

GENERAL RESPONSES

1. Plaintiffs' alleged undisputed material facts based on Average Wholesale Price ("AWP") are immaterial and irrelevant to this motion, limited as it is to issues relating to the FUL. As Defendants point out in their own motion for summary judgment, CMS officials could not recall ever having used an AWP as the basis for a FUL. *See* Local Rule 56.1 Stmt. of

Undisputed Material Facts Supporting Defs.’ Joint Mot. for Summary Judgment on Pls.’ “FUL Fraud” Claims (“Defs.’ 56.1 Stmt.”) at ¶ 34, filed May 15, 2009 [Docket No. 6054].

2. Roxane disputes Plaintiffs’ alleged undisputed material facts based on Wholesale Acquisition Cost (“WAC”) to the extent that Plaintiffs allege facts related to WAC that extend beyond early 1998, on the grounds that Roxane stopped reporting WACs for its multisource products in late 1997 or early 1998. Pls.’ Ex. C, 5/10/07 Waterer Dep. at 425:1-19.

3. Roxane further disputes Plaintiffs’ alleged undisputed material facts to the extent they imply that the State of New York (“New York”) or the New York Department of Health (“NYDOH”), the entity responsible for reimbursing Medicaid providers in New York, did not have access to actual prices for the Roxane Subject Drugs. New York and the NYDOH had access to Average Manufacturer Prices (“AMPs”). *See* Exhibit A, 12/12/08 Roxane 30(b)(6) Deposition (Judy Waterer) (hereafter, “Ex. A, 12/12/08 Waterer Dep.”) at 170:10-22 (“[States] would have access to [AMPs], either directly if the government chose to share it with them under a confidentiality agreement or indirectly by doing a simple calculation on the rebates they get every quarter from [Roxane].”). In fact, since 1991, New York has had access to AMPs through the Unit Rebate Amounts (“URAs”) provided to it on a quarterly basis through the federal Medicaid Rebate Program. 42 U.S.C. § 1396r-8(b)(3)(A) (1991).

4. Roxane further disputes Plaintiffs’ recitation of the purportedly undisputed facts to the extent that it implies that New York set reimbursement rates in the belief that they were based on the actual selling prices for the Roxane Subject Drugs. As set forth in Defendants’ summary judgment papers, NYDOH has long understood that “a pharmacy’s acquisition cost for a drug is likely to be lower than the prices quote[d] in third-party pricing compendia such as the Red Book or First DataBank.” *See* Defs.’ 56.1 Stmt. at ¶¶ 60-63 (Aff. of Cesar A. Perales, at ¶ 2

& Ex. A). New York's knowledge is further demonstrated by the fact that during the notice-and-comment period for the FUL in 1986, the New York Department of Social Services (the predecessor to NYDOH) commented on three proposed alternatives for establishing the FUL and specifically urged the Health Care Financing Administration ("HCFA") not to base the FUL on published prices because "the advertised price found in the Red Book or the Blue Book may not reflect the actual purchase prices." *Id.* at ¶¶ 60-61.

SPECIFIC RESPONSES

1. The Roxane Drugs and NDCs that have been examined in connection with this motion are set forth in Exhibit A hereto. This exhibit also sets forth Roxane's Published AWP's and WACs for these Drugs and NDCs. The exhibit notes which NDCs are associated with package sizes that set the FUL.

Roxane's Response to Alleged Fact No. 1: Roxane does not dispute that Exhibit A to Plaintiffs' Roxane-Specific Statement purports to (1) list the Roxane drugs and NDCs that Plaintiffs have examined in connection with their motion, (2) set forth Roxane's published AWP's and WACs for these drugs and NDCs, and (3) note which NDCs are associated with the package sizes that set the FUL. Roxane disputes the data set forth in Exhibit A to the extent it is not properly supported by evidence in the record. Plaintiffs have cited no evidentiary basis for the data set forth in Exhibit A, as is required by Local Rule 56.1. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006) (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings).

2. The specific Roxane drugs at issue are the Albuterol .83 mg/ml Solution and Ranitidine 150 MG Tablet.

Roxane's Response to Alleged Fact No. 2: Roxane does not dispute that Roxane's Albuterol 0.83mg solution and Ranitidine 150mg tablet are drugs at issue in Plaintiffs' motion. Plaintiffs, however, have cited no evidentiary basis for this alleged fact, as is required by Local Rule 56.1. *See O'Brien*, 440 F. Supp. 2d at 5 n.1.

3. **Roxane has entered into and executed the federal Medicaid rebate agreement pursuant to 42 U.S.C. § 1396r-8. See Affirmative Defenses of Boehringer Ingelheim Roxane, Inc. to the Revised First Amended Consolidated Complaint (“Roxane Answer”) [Dkt #4851] at ¶132.**

Roxane’s Response to Alleged Fact No. 3: Roxane does not dispute that Roxane has entered into and executed the federal Medicaid Rebate agreement with the Secretary of Health and Human Services on behalf of all States. This fact, however, is immaterial to Plaintiffs’ motion.

4. **Roxane knew that eligibility for reimbursement by Medicaid was an important issue for its customers. See Boehringer Ingelheim Roxane, Inc. 30(b)(6) (Judy Waterer) 5/9/07 Deposition Transcript (Exhibit B) at 41:1-10 (hereinafter, “Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B)”).**

Roxane’s Response to Alleged Fact No. 4: Roxane disputes that it “knew that eligibility for reimbursement by Medicaid was an important issue for its customers.” This alleged fact is not properly supported by the evidence in the record. *O’Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that she did not “believe [Roxane] could exist as a pharmaceutical company unless [it] agreed to participate in the [Medicaid drug] programs, because nobody would buy [its] drugs. So it’s pretty much required.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 41:6-10.

5. **At all times relevant hereto, Roxane reported and/or controlled its published WACs. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 70:3-15; Boehringer Ingelheim Roxane, Inc. 30(b)(6) (Judy Waterer) 5/10/07 Deposition Transcript (Exhibit C) at 420:5-426:16; 446:20-447:3 (hereinafter, “Roxane 30(b)(6) (Waterer) 5/10/07 Dep. (Exhibit C)”); Boehringer Ingelheim Roxane, Inc. 30(b)(6) (Judy Waterer) 5/11/07 Deposition Transcript (Exhibit D) at 662:13-673:13; 712-714:13 (hereinafter, “Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D)”).** Roxane has only one WAC at any given time and reported the same WAC to all publishing compendia. *See Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 616:18-21; 650:13-23.*

Roxane’s Response to Alleged Fact No. 5: Roxane disputes that “[a]t all times relevant hereto, Roxane reported and/or controlled its published WACs.” This alleged fact is not properly

supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that “[w]hen a product launches and when there are changes made, it [the WAC] would be reported.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 70:11-15. Ms. Waterer further testified that “it was not industry practice to report WAC on multisource products” and that Roxane stopped reporting WACs for multisource products to pricing compendia in 1997 or 1998. Pls.’ Ex. C, 5/10/07 Waterer Dep. at 425:1-19. Ms. Waterer testified that the decision to stop reporting WACs to pricing compendia was “just another thing [Roxane] had to do to be in line with normal generic practices.” Pls.’ Ex. D, 5/11/07 Waterer Dep. at 669:13-19. But Roxane could not control when the compendia stopped reporting Roxane’s WACs. *See* Exhibit B, 5/9/07 Roxane 30(b)(6) Deposition (Judy Waterer) (hereafter, “Ex. B, 5/9/07 Waterer Dep.”) at 130:4 - 131:25; Pls.’ Ex. C, 5/10/07 Waterer Dep. at 421:21 - 422:17 (“They were continuing to report WAC prices that we had told them were no longer valid.”).

With respect to the second sentence of Alleged Fact No. 5, Roxane disputes that it “has only one WAC at any given time and reported the same WAC to all publishing compendia.” This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that wholesalers have the same WAC for any particular drug. Pls.’ Ex. D, 5/11/07 Waterer Dep. at 616:18-21. And Ms. Waterer further testified that each of Roxane’s databases had the same WAC for each drug, “unless there was a typo or it was a database that was no longer kept current.” Pls.’ Ex. D, 5/11/07 Waterer Dep. at 650:13-23.

6. Roxane reported AWP to the publishing compendia. *See* Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 68:14-25; Roxane 30(b)(6) (Waterer) 5/10/07 Dep. (Exhibit C) at 446:10-19.

Roxane’s Response to Alleged Fact No. 6: Roxane does not dispute that Roxane provided AWP to the publishing compendia. Alleged Fact No. 6, however, is immaterial to

Plaintiffs' motion because, as set forth in General Response No. 1 above, CMS did not consider AWP's in setting FULs. *See* Defs.' 56.1 Stmt. at ¶ 34.

7. All published AWP's reflect what Roxane submitted to the publishing compendia. *See* Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 82:16-84:4; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 650:13-23.

Roxane's Response to Alleged Fact No. 7: Roxane disputes that "[a]ll published AWP's reflect what Roxane submitted to the publishing compendia." This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that Roxane "would not want [third-party compendia] putting false and misleading information out there," but Roxane would only check the reported price when the compendia would send a request to Roxane for verification of a price. Pls.' Ex. B, 5/9/07 Waterer Dep. at 82:25-83:11 ("Q. But Roxane does nothing to monitor the published prices, correct? A. To the best of my knowledge, with the exception of the times when they have sent us items saying, Please verify this, [...] that is when we look at how they have our prices listed.")).

More generally, as this Court knows from the *McKesson* case, no manufacturer "controlled" its AWP's. AWP's were published by the national pricing compendia, including specifically First DataBank, that unilaterally and over some manufacturers' objections raised AWP's for their products as a result of an agreement with McKesson and other wholesalers. The *McKesson* case makes plain that First DataBank did not function as the manufacturers' agent and the manufacturers did not "control" their AWP's or other published prices. *See, e.g., New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 244 F.R.D. 79 (D. Mass. 2007).

And in any event, Alleged Fact No. 7 is immaterial to Plaintiffs' motion because, as set forth in General Response No. 1, CMS did not consider AWP's in setting FULs. *See* Defs.' 56.1 Stmt. at ¶ 34.

8. Roxane knew and controlled the AWP's and WAC's for its drugs that were published by the national drug pricing compendia. Both Redbook and First Databank would send requests to Roxane to verify the accuracy of the AWP's and WAC's for its drugs and Roxane would respond with corrections if errors were found. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 62:7-63:17; 135:15-137:24; Roxane 30(b)(6) (Waterer) 5/10/07 Dep. (Exhibit C) at 454:19-458:7; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 647:21- 650:12.

Roxane's Response to Alleged Fact No. 8: Roxane disputes that it "knew and controlled the AWP's and WAC's for its drugs that were published by the national drug pricing compendia." This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that Roxane would only check the reported price when the compendia would send a request to Roxane for verification of a price. Pls.' Ex. B, 5/9/07 Waterer Dep. at 82:25-83:11 ("Q. But Roxane does nothing to monitor the published prices, correct? A. To the best of my knowledge, with the exception of the times when they have sent us items saying, Please verify this, [...] that is when we look at how they have our prices listed."). And, as stated more fully in Roxane's Response to Alleged Fact No. 7, no manufacturer "controlled" its AWP's. The *McKesson* case makes plain that manufacturers did not "control" their AWP's or other published prices. See, e.g., *New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 244 F.R.D. 79 (D. Mass. 2007).

With respect to the second sentence of Alleged Fact No. 8, Roxane acknowledges that "[t]he pricing compendia would occasionally send us a voluminous report and say, Please check this for accuracy. And we would go through and verify if their records matched our records. And if they didn't, we'd cross it out and put in the correct price, as we knew it, and send it back and hope that they would adjust it." Pls.' Ex. B, 5/9/07 Waterer Dep. at 62:19-63:1.

But to the extent that Alleged Fact No. 8 addresses WACs, Ms. Waterer testified that "it was not industry practice to report WAC on multisource products" and that Roxane stopped reporting WACs for multisource products to pricing compendia in 1997 or 1998. Pls.' Ex. C,

5/10/07 Waterer Dep. at 425:1-19. And, to the extent that Alleged Fact No. 8 addresses AWP, it is immaterial to Plaintiffs' motion because, as set forth in General Response No. 1, CMS did not consider AWP in setting FULs. *See* Defs.' 56.1 Stmt. at ¶ 34.

9. For generic products Roxane was the first to launch, Roxane sets an AWP upon product launch at 10% below the brand AWP. *See* Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 69:1-23.

Roxane's Response to Alleged Fact No. 9: Roxane disputes that, in every instance, "for generic products Roxane was the first to launch, Roxane sets an AWP upon product launch at 10% below the brand AWP." This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that when Roxane launches a new generic drug, the "most common thing to do is take 10 percent of the brand's AWP at launch. There are instances when that does not occur." Ex. A, 12/12/08 Waterer Dep. at 34:19-22. Alleged Fact No. 9, however, is immaterial to Plaintiffs' motion because, as set forth in General Response No. 1, CMS did not consider AWP in setting FULs. *See* Defs.' 56.1 Stmt. at ¶ 34.

10. When Roxane launched a product into existing generic competition, it set the AWP at a level comparable to the AWP of the competing products. *See* Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 69:1-23; Roxane 30(b)(6) (Waterer) 5/10/07 Dep. (Exhibit C) at 448:14-10; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 604:1-18.

Roxane's Response to Alleged Fact No. 10: Roxane does not dispute that, when it launched a product into an established market, Roxane typically "would have looked at what all of the competitors' AWP were that were available and put [Roxane's] AWP so that it was in the same price range as theirs." Pls.' Ex. C, 5/10/07 Waterer Dep. at 449:2-10. Alleged Fact No. 10, however, is immaterial to Plaintiffs' motion because, as set forth in General Response No. 1, CMS did not consider AWP in setting FULs. *See* Defs.' 56.1 Stmt. at ¶ 34.

11. Roxane's AWP has no connection whatsoever to actual prices charged by Roxane to any customers. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 70:16-71:9; 72:17- 20; 79:19-80:13; 112:5-119:14; Waterer Deposition Exhibit No. 3 (Exhibit B); 123:5-129:15; Waterer Deposition Exhibit No. 4 (Exhibit B); Roxane 30(b)(6) (Waterer) 5/10/07 Dep. (Exhibit C) at 447:9-20; 454:7-18.

Roxane's Response to Alleged Fact No. 11: Roxane does not dispute that AWP's "do not reflect an actual price that anybody pays [Roxane] for [Roxane's drugs]." Pls.' Ex. B, 5/9/07 Waterer Dep. at 79:23-25. In fact, nobody in the industry thought that AWP's bore a predictable relationship to market prices for generic drugs. Ex. A, 12/12/08 Waterer Dep. at 26:7-28:1 ("[W]e've never heard [AWP] described as anything else. In many, many, many years in the industry, [AWP] has had a recognized definition or meaning that did not mean it was an actual, some kind of calculated average of prices in the marketplace."). And "the government would have every reason to know that [AWP] was not defined in the industry or in any general practice as some kind of actual average of wholesale prices." Ex. A, 12/12/08 Waterer Dep. at 138:14-139:11. This is because "[i]t would be irrational to think that anybody doing that reimbursement would think that that's the price that a customer paid for it, that they would be willing to accept reimbursement way below what their acquisition cost was." Ex. A, 12/12/08 Waterer Dep. at 29:9-14.

But in any event, Alleged Fact No. 11 is immaterial to Plaintiffs' motion because, as set forth in General Response No. 1, CMS did not consider AWP's in setting FULs. See Defs.' 56.1 Stmt. at ¶ 34.

12. Roxane's reported WACs are always higher than contract prices. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 150:3-151:11; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 584:2-10; Boehringer Ingelheim Roxane, Inc. 30(b)(6) (Judy Waterer) 7/24/07 Deposition Transcript (Exhibit E) at 753:10-756:7, (hereinafter, "Roxane 30(b)(6) (Waterer) 7/24/07 Dep. (Exhibit E)").

Roxane's Response to Alleged Fact No. 12: Roxane does not dispute that Ms. Waterer agreed that "WAC prices are higher than contract prices." Pls.' Ex. B, 5/9/07 Waterer Dep. at

151:9-11. Ms. Waterer testified that Roxane “set WAC to be something that was, in general, higher than our highest contract price, so that there would still be a chargeback issued.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 150:19-22. And Ms. Waterer testified that “it was not industry practice to report WAC on multisource products” and that Roxane stopped reporting WACs for multisource products to pricing compendia in 1997 or 1998. Pls.’ Ex. C, 5/10/07 Waterer Dep. at 425:1-19.

13. Most customers who purchase Roxane multisource products have contracts with Roxane. See Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 552:18-554:17. All customers who have contracts with Roxane pay contract prices. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 52:12-17; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 581:23-582:7; Roxane 30(b)(6) (Waterer) 7/24/07 Dep. (Exhibit E) at 761:22-762:8. Contract prices are below WAC even before any rebates, fees, credits are paid. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 72:21-73:8; 150:3-151:14; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 584:2-10; Roxane 30(b)(6) (Waterer) 7/24/07 Dep. (Exhibit E) at 753:10-756:7. Contract prices are further reduced by subsequent rebates, fees and credits. See Roxane 30(b)(6) (Waterer) 7/24/07 Dep. (Exhibit E) at 788:17-792:1.

Roxane’s Response to Alleged Fact No. 13: Roxane acknowledges that most customers who purchase Roxane multisource products have contracts with Roxane. See Pls.’ Ex. D, 5/11/07 Waterer Dep. 553:4-13. With respect to the second sentence of Alleged Fact No. 13, Roxane disputes that “all customers who have contracts with Roxane pay contract prices.” This alleged fact is not properly supported by the evidence in the record. *O’Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that contract prices are “offer[ed] to pharmac[ies], pharmacy chains, customers that are actually dispensing the product.” Pls.’ Ex. E, 7/24/07 Waterer Dep. at 762:5-8. Ms. Waterer also testified that contract prices are “discussed” and “agreed upon.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 52:12-17. And Ms. Waterer testified that “if there was a contract on an individual product, it would have sold at the contract price.” Pls.’ Ex. D, 5/11/07 Waterer Dep. at 582:5-7.

With respect to the third sentence of Alleged Fact No. 13, Roxane disputes that “[c]ontract prices are below WAC even before any rebates, fees, credits are paid.” This alleged fact is not properly supported by the evidence in the record. *O’Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that, “[i]f the wholesaler does not sell [a drug] through a contract where we would honor a lower price, it will sell at WAC.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 73:3-5. Ms. Waterer also testified that Roxane “set WAC to be something that was, in general, higher than our highest contract price, so that there would still be a chargeback issued.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 150:19-22. Plaintiffs offer no support for their assertion that contract prices are below WAC *even before* any rebates, fees, or credits are paid. None of the evidence cited discusses whether rebates, fees, or other credits were ever included in the contract price. With respect to the fourth sentence of Alleged Fact No. 13, Roxane disputes that “[c]ontract prices are further reduced by subsequent rebates, fees, and credits.” Ms. Waterer testified that: “In some instances, if we had a direct purchasing contract, a direct warehousing contract customer, there may have been performance incentive rebates that would have been, depending on their performance, within the terms of whatever [the] contract stipulation was. There may have been rebates that they got subsequent to that.” Pls.’ Ex. E, 7/24/07 Waterer Dep. at 791:16-792:1.

14. Roxane also enters into contracts with wholesalers. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 48:21-49:17; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 554:18-555:19; 558:15-559:23; 570:8-572:12. Some wholesaler contracts provide for product-specific pricing and incentives. See Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 585:18-590:10; Waterer Deposition Exhibit 72 (Exhibit D); 616:22-619:24. Product specific pricing is below WAC. See Waterer 5/9/07 30(b)(6) Dep. (Exhibit B) at 616:22-619:24. Product specific incentives (rebates/fees/allowances) reduce wholesaler’s acquisition cost for the relevant Roxane product. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 88:5-16; Roxane 30(b)(6) (Waterer) 7/24/07 Dep. (Exhibit E) at 788:17-792:1.

Roxane’s Response to Alleged Fact No. 14: Roxane acknowledges that it enters into contracts with some wholesalers. With respect to the second sentence of Alleged Fact No. 14,

Roxane disputes that “[s]ome wholesaler contracts provide for product-specific pricing and incentives.” This alleged fact is not properly supported by the evidence in the record. *O’Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that contracts with wholesalers were categorized based on the wholesalers’ level of compliance with the contract, and “depending on the level of compliance that the category demanded, they would get increasingly preferential pricing.” Pls.’ Ex. D, 5/11/07 Waterer Dep. at 588:2-8, 588:14-590:9. Ms. Waterer also testified that wholesaler contracts typically include a “prompt-payment discount,” and “sometimes, at the launch of a product, [Roxane] may offer a discount.” Pls.’ Ex. D, 5/11/07 Waterer Dep. 617:2-13. A discount offered at launch is “[g]enerally in recognition of the fact that [wholesalers are] going to have to update all of their systems and find new shelf space and rearrange their inventory[.]” Pls.’ Ex. D, 5/11/07 Waterer Dep. 617:16-21.

With respect to the third sentence of Alleged Fact No. 14, Roxane disputes that “[p]roduct specific pricing is below WAC.” This alleged fact is not properly supported by the evidence in the record. *O’Brien*, 440 F. Supp. 2d at 5 n.1. The portion of the record cited contains Ms. Waterer’s discussion of the prompt-payment and launch discounts. Pls.’ Ex. D, 5/11/07 Waterer Dep. 617:2-21. And with respect to both the third and fourth sentences, the definition of WAC is “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, *not including prompt pay or other discounts, rebates or reductions in price. . . .*” 42 U.S.C. § 1395w-3a(c)(6)(B) (2005). Thus, by definition, the WAC is likely to be higher than a wholesaler’s net price for Roxane products, because it is exclusive of “prompt pay or other discounts, rebates or reductions in price.”

15. Roxane’s definition of AWP was merely “functional” in the sense that for generic products, Roxane sets AWP at 10% below the competing brand product, and didn’t “think about” it anymore. In other words, AWP, once set for a Roxane generic product, remains the same regardless of changes in actual market prices. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 69:1-14.

Roxane’s Response to Alleged Fact No. 15: Roxane acknowledges that AWP is a “functional term [that] is most commonly at launch tied to a brand’s AWP.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 69:17-23. Ms. Waterer testified that “[i]t is most commonly set at 10 percent below the brand’s AWP when a product launches. And for the most part, that’s about as much as we think about AWP.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 69:17-23. With respect to the second sentence, Roxane disputes that “AWP, once set for a Roxane generic product, remains the same regardless of changes in actual market prices.” This alleged fact is not properly supported by the evidence in the record. *O’Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that Roxane understood that industry practice for generic products was that, after launch, the AWP typically was not changed. Ex. A, 12/12/08 Waterer Dep. at 94:17-95:5. Two exceptions to this rule are: (1) when a Roxane drug becomes a sole-source drug, Roxane may increase all of its prices across the board, including the AWP; and (2) when a customer complains and points out that Roxane’s AWP is significantly lower than its competitors. Ex. B, 5/9/07 Waterer Dep. at 74:11-76:7.

In any event, Alleged Fact No. 15 is immaterial to Plaintiffs’ motion because, as set forth in General Response No. 1, CMS did not consider AWP in setting FULs. See Defs.’ 56.1 Stmt. at ¶ 34.

16. Roxane enters into contracts with other relevant Pharmacy Providers ("Non-retail PPs"). *See* Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 48:21-50:25; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 584:2-585:11. Some non-retail PP contracts provide for baseline rebates. *See* Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 87:1-88:4. Baseline rebates reduce non-retail PPs' acquisition cost for all Roxane products. *See* Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 87:1-88:4.

Roxane's Response to Alleged Fact No. 16: Roxane disputes that "Roxane enters into contracts with other relevant Pharmacy Providers." This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that Roxane enters contracts with "warehousing chains" and "buying groups," which are "conglomeration[s] of multiple pharmacies that have agreed to participate within the buying group." Pls.' Ex. B, 5/9/07 Waterer Dep. at 49:6-24. Ms. Waterer also testified that Roxane may contract with "mail-order purchasers" and "long-term care, staff model HMO[s]." Pls.' Ex. D, 5/11/07 Waterer Dep. at 584:7-15.

With respect to the second and third sentences of Alleged Fact No. 16, Roxane disputes that any of its contracts provide for "baseline rebates." This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that some contracts were categorized based on the level of compliance with the contract, and "depending on the level of compliance that the category demanded, they would get increasingly preferential pricing." Pls.' Ex. D, 5/11/07 Waterer Dep. at 588:2-8, 588:14-590:9. Ms. Waterer also testified that contracts typically include a "prompt-payment discount," and "sometimes, at the launch of a product, [Roxane] may offer a discount." Pls.' Ex. D, 5/11/07 Waterer Dep. 617:2-13.

And, as previously discussed in Roxane's Response to Alleged Fact No. 14, the very definition of WAC is "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, *not including prompt pay or other discounts, rebates or*

reductions in price. . . .” 42 U.S.C. § 1395w-3a(c)(6)(B) (2005). Thus, by definition, an “acquisition cost” is exclusive of “prompt pay or other discounts, rebates or reductions in price.”

17. Roxane’s reported prices are inconsistent with the definition of reported prices in the OIG 2003 Compliance Guidelines. See Boehringer Ingelheim Roxane, Inc. 30(b)(6) (Judy Waterer) 12/12/08 Deposition Transcript (Exhibit F) at 149:17-155:8 (hereinafter, “Roxane 30(b)(6) (Waterer) 12/12/08 Dep. (Exhibit F)”) (interpreting the OIG Guidelines to say simply that the reported prices must be what they are represented to be, and because Roxane used the industry definition of AWP (which bears no relation to actual prices generally and currently available) Roxane must therefore be in compliance); Deposition of Thomas Russillo dated 1/8/09 (“Exhibit G”) at 239:11-242:8 (Roxane was aware of the OIG Guidelines, but did not consider them in approving prices for publication at any time thereafter).

Roxane’s Response to Alleged Fact No. 17: Roxane disputes that “Roxane’s reported prices are inconsistent with the definition of reported prices in the OIG 2003 Compliance Guidelines,” and Roxane disputes Plaintiffs’ characterization of Ms. Waterer’s cited testimony. These alleged facts are not facts, but rather are arguments and mischaracterizations that are not properly supported by the evidence in the record. *O’Brien*, 440 F. Supp. 2d at 5 n.1. In response to being read “a paragraph entitled integrity of data used to establish or determine government reimbursement,” Ms. Waterer responded, “I don’t recall specifically reading that, but I would think that we would have a responsibility to report pricing that was correct.” Pls.’ Ex. F, 12/12/08 Waterer Dep. at 150:1-151:3. Ms. Waterer went on to testify, “I don’t specifically recall hearing anything in that [paragraph] that defined that the government believed that AWP was anything other than what the industry understood it to be.” Pls.’ Ex. F, 12/12/08 Waterer Dep. at 151:11-14.

And nobody in the industry thought that AWP’s bore a predictable relationship to market prices for drugs. Ex. A, 12/12/08 Waterer Dep. at 26:7-28:1 (“[W]e’ve never heard [AWP] described as anything else. In many, many, many years in the industry, [AWP] has had a recognized definition or meaning that did not mean it was an actual, some kind of calculated

average of prices in the marketplace.”). In fact, “the government would have every reason to know that [AWP] was not defined in the industry or in any general practice as some kind of actual average of wholesale prices.” Ex. A, 12/12/08 Waterer Dep. at 138:14-139:11. This is because “[i]t would be irrational to think that anybody doing that reimbursement would think that that’s the price that a customer paid for it, that they would be willing to accept reimbursement way below what their acquisition cost was.” Ex. A, 12/12/08 Waterer Dep. at 29:9-14.

Roxane also disputes Plaintiffs’ characterization of Mr. Russillo’s testimony. Mr. Russillo was asked if “Roxane considere[d] the OIG guidance with respect to AWP in the formulation of any Roxane pricing practices,” and Mr. Russillo responded, “[I]f there was any consideration made, and I don’t recall at the time what we were doing, but we would have certainly taken that into account.” Pls.’ Ex. G, 1/8/09 Russillo Dep. at 241:1-10. Mr. Russillo went on to testify, “I’m sure that we had legal review of the guidance. And if there was anything that needed to be changed, we were told. But I don’t recall being told to change anything.” Pls.’ Ex. G, 1/8/09 Russillo Dep. at 242:5-8.

In any event, Alleged Fact No. 17 is immaterial to Plaintiffs’ motion because, as set forth in General Response No. 1, CMS did not consider AWP in setting FULs. *See* Defs.’ 56.1 Stmt. at ¶ 34.

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Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of DEFENDANT BOEHRINGER INGELHEIM ROXANE, INC.'S RESPONSE TO PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO BOEHRINGER INGELHEIM ROXANE, INC. was delivered to all counsel of record by sending a copy to LexisNexis File and Serve, on June 29, 2009, for posting and notification to all parties.

s/ Lauren O. Casazza

Lauren O. Casazza